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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/811,824 03/20/2001 George P. Anderson 01997-282001 / MIT Case 8422

26161 7590 08/07/2003

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 08/07/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,824

Applicant(s)

ANDERSON ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 57 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:
 - I. Claims 1-56, drawn to a composition comprising an inorganic particle, a linking group and a macromolecule, wherein the distal end of the linking group linked to the inorganic particle, and the proximal end of the linking group linked to the macromolecule via ionic conjugation; and a method of forming an ionic conjugate, classified in class 428, subclass 402.4, class 257, subclass 65, and class 435, subclass 7.1.

Should Invention I be elected, applicant is required to select one first semiconductor material from claims 3, 23 and 37; one second semiconductor material from claims 7 and 41; one macromolecule (polypeptide or polynucleotide) from claims 15 and 21. Each semiconductor material or each macromolecule has different chemical property, different function, and produce different effect, thus, is a distinct chemical entity. For example, in semiconductor material, CdSe of Group II-VI can be used to make materials which absorb and emit in the visible region, while InP of Group III-V have bulk bandgaps in the infrared wavelengths (Marcel Bruchez, Jr. Doctoral Dissertation (1999, page 10); Regarding macromolecule, polypeptide can be used to assay or purify the cognate receptor, while polynucleotide can be used in nucleotide hybridization assay, thus they are patentably distinct. This is not species election.

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- II. Claims 57 and 58, drawn to a method of detecting the presence of a predetermined species in a solution using an ionic conjugate, wherein the ionic conjugate contains an inorganic particle electrostatically associated with an macromolecule, classified in class 428, subclass 402.4, class 257, subclass 65, and class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions I and II are different processes, one of making the product (Invention I) and one of using the product (Invention II). The two methods use different materials, have different method steps and produce different results. The practice of the process of Invention I does not require the process of Invention II.

The product of Invention I and the methods of Invention II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of Invention II can be practiced with a different product such as a fluorescent-tagged organic molecule (page 1, lines 14-21 of the specification).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the recognized divergent subject matter, and because Inventions I and II require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Harold Fox on July 14, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-56, CdSe in Group II-VI as the first semiconductor material, ZnS in Group II-VI as the second semiconductor material, and polypeptide as the macromolecule. Affirmation of this election must be made by applicant in replying to this Office action. Claims 57 and 58 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Upon reconsideration, all the first or second semiconductor materials listed as Group II-VI compounds, and the polypeptide and polynucleotide as macromolecule will be examined.

Claim Objections

3. Claims 3, 4, 7, 23, 37, 38 and 41 are objected to because the claim contains recitation of non-elected semiconductor materials.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-9, 11-13, 15, 16, 35-43, 45-47, 49 and 50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 16-18, 29-32, 37, 38 and 45-57 of U. S. Patent 6,306,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-9, 11-13, 15, 16, 35-43, 45-47, 49 and 50 in the instant application discloses a composition comprising an inorganic particle, a linking group which binds to the outer surface of the inorganic particle and has a first ionizable moiety, and a macromolecule having a second ionizable moiety, wherein the first and the second ionizable moieties associate the inorganic particle with the macromolecule to form an ionic conjugate, and a method of forming the ionic conjugate. This is obvious in view of claims 1-10, 16-18, 29-32, 37, 38 and 45-57 of the patent which discloses a composition comprising a first member of a binding pair; a semiconductor nanocrystal core linked to the first member, and an outer layer including a ligand comprising a multidentate molecule or a molecule having formula of $H_zX((CH_2)_nCO_2H)_y$, where the link between the first member of a binding pair and the nanocrystal comprising a linking group for attachment to the nanocrystal and a second portion comprising a hydrophilic group which links to the first member by hydrophilic or electrostatic interaction, and the first member can be a protein. Both the claims of instant application and the claims of the patent are directed to a composition comprising a

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semiconductor nanocrystal, a linking group which binds to the outer surface of the nanocrystal and has an ionizable moiety, and a macromolecule having an ionizable moiety, wherein the nanocrystal associates with the macromolecule via ionic interaction. Thus, claims 1-9, 11-13, 15, 16, 35-43, 45-47, 49 and 50 in present application and claims 1-10, 16-18, 29-32, 37, 38 and 45-57 of the patent are obvious variations of a composition comprising a semiconductor nanocrystal, a linking group which binds to the outer surface of the nanocrystal and has an ionizable moiety, and a macromolecule having an ionizable moiety, the nanocrystal and the macromolecule form an ionic conjugate.

5. Claims 1-5, 8, 9, 11-12, 15, 16, 35-39, 42, 43, 45-46, 49 and 50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U. S. Patent 6,326,144. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-5, 8, 9, 11-12, 15, 16, 35-39, 42, 43, 45-46, 49 and 50 in the instant application discloses a composition comprising an inorganic particle, a linking group which binds to the outer surface of the inorganic particle and has a first ionizable moiety, and a macromolecule having a second ionizable moiety, wherein the first and the second ionizable moieties associate the inorganic particle with the macromolecule to form an ionic conjugate, and a method of forming the ionic conjugate. This is obvious in view of claims 1-72 of the patent which discloses a composition comprising a compound; a semiconductor nanocrystal linked to the compound by a ligand of the formula of $H_zX((CH_2)_nCO_2H)_y$, where the compound has an affinity for a biological target, and the affinity of the compound to the biological target can be hydrophilic or electrostatic attraction, and wherein the compound can be a protein, a peptide or a nucleic acid. Both the claims of instant application and the claims of the

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patent are directed to a composition comprising a semiconductor nanocrystal, a linking group which binds to the outer surface of the nanocrystal and has an ionizable moiety, and a macromolecule having an ionizable moiety, wherein the nanocrystal associates with the macromolecule via ionic interaction. Thus, claims 1-5, 8, 9, 11-12, 15, 16, 35-39, 42, 43, 45-46, 49 and 50 in present application and claims 1-72 of the patent are obvious variations of a composition comprising a semiconductor nanocrystal, a linking group which binds to the outer surface of the nanocrystal and has an ionizable moiety, and a macromolecule having an ionizable moiety, wherein the nanocrystal and the macromolecule have ionic interaction.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a semiconductor nanocrystal, a linking group which binds to the outer surface of the inorganic particle and has an ionizable moiety, and a protein having an ionizable moiety, wherein the nanocrystal and the protein form an ionic conjugate, and a method of forming the ionic conjugate; or hybridization of a nucleic acid with a nanoparticle having oligonucleotide attached thereto, or a composition comprising a fluorescent semiconductor nanocrystal, associated with a compound that has affinity and can physically interact with a biological target as indicated in the prior art, does not reasonably provide enablement for a composition comprising an inorganic particle, a linking group which binds to the outer surface of the inorganic particle and has an ionizable moiety, and a macromolecule

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having an ionizable moiety, wherein the inorganic particle and the macromolecule forms an ionic conjugate, and a method of forming the ionic conjugate, where the inorganic particle and the macromolecule are not defined. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-56 are directed to a composition comprising an inorganic particle, a linking group, and a macromolecule or a fusion protein, wherein the inorganic particle and the macromolecule forms an ionic conjugate (claims 1-34), and a method of forming the ionic conjugate (claims 35-56). The specification, however, only discloses cursory conclusions without data supporting the findings, which states that an ionic conjugate forms through self-assembly in which inorganic particles electrostatically associate with at least one macromolecule (page 2). There are no indicia that the present application enables the full scope in view of an ionic conjugate comprising an inorganic particle, a linking group, and a macromolecule, and a method of making the ionic conjugate as discussed in the stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claims is enabled. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the absence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breath of the claims:

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The breath of the claims is broad and encompasses unspecified variants regarding inorganic particles and macromolecules in the composition, which are not adequately described or demonstrated in the specification.

(2). The absence or presence of working examples:

There are no working examples indicating the claimed variants except for an ionic conjugate of semiconductor nanoparticles (CdSe-Zn-S) with Maltose binding protein (MBP)-leucine zipper fusion protein or with protein G-leucine zipper fusion protein (pages 22-29).

(3). The state of the prior art and relative skill of those in the art:

The prior art indicates hybridization of a nucleic acid with a nanoparticle having oligonucleotide attached thereto (Mirkin *et al.*, WO 98/04740, February 1998) and a composition comprising a fluorescent semiconductor nanocrystal associated with a compound that has affinity and can physically interact with a biological target (Bawendi *et al.*, U. S. Patents, 6,306,610 and 6,326,144). However, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide more teachings on the make and use of ionic conjugates containing various inorganic particles and various macromolecules to be considered enabling for the claimed method.

(4). Predictability or unpredictability of the art:

The specification has shown the make of ionic conjugates of semiconductor nanoparticles (CdSe-Zn-S) with Maltose binding protein (MBP)-leucine zipper fusion protein or with protein G-leucine zipper fusion protein (pages 22-29). However, the specification does not provide the make/use of ionic conjugates containing various inorganic particles and various macromolecules, the invention is highly unpredictable regarding the effects of various ionic conjugates.

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(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to an ionic conjugate comprising an inorganic particle, a linking group, and a macromolecule or a fusion protein, and a method of forming the ionic conjugate. The specification has shown the make of ionic conjugates of semiconductor nanoparticles (CdSe-Zn-S) with Maltose binding protein (MBP)-leucine zipper fusion protein or with protein G-leucine zipper fusion protein (pages 22-29). However, the specification has not demonstrate the making and use of various ionic conjugates containing different inorganic particles and different macromolecules. There is no working example indicating the claimed variants except for an ionic conjugate of a semiconductor nanoparticle with a fusion protein. The specification has not provided sufficient teachings on the make/use of various ionic conjugates, which encompassed by the claims. Since the specification fails to provide sufficient teaching on the make/use of ionic conjugates containing various inorganic particles and macromolecule, it is necessary to carry out further experimentation to assess the effects of various ionic conjugates.

(6). Nature of the Invention

The scope of the claims encompasses various ionic conjugates, but the specification does not provide sufficient teachings on the make/use of these ionic conjugates and the effects of these conjugates. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, the scope of the claim is broad, the working example does not demonstrate the claimed variants, the art is unpredictable regarding the effects of the conjugates, and the teaching in the specification are limited, therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of these ionic conjugates.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4-7 and 38-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4-7 and 38-41 are indefinite because of the use of the term “mixtures thereof”. The term “mixtures thereof” renders the claim indefinite, it is unclear what components and what amounts of each component are contained in the mixture. Note that Markush group is cited in the claim, where close language should be used, however, the term “mixtures thereof” is an open language. Claims 5-7 and 39-41 are rejected for being dependent on a rejected claim and not correcting the deficiency of the claim from which it depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

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international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-5, 8-12, 15, 35-39, 42-46 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Mirkin *et al.* (WO 98/04740, February 1998).

Mirkin *et al.* teach a method of detecting nucleic acids by contacting a nucleic acid with one or more types of nanoparticles having oligonucleotides attached thereto, where the nucleic acid has at least two portions and the oligonucleotides on the nanoparticles have a sequence complementary to the sequence of one of the portions of the nucleic acid, and the contacting takes place under conditions effective to allow hybridization of the oligonucleotides on the nanoparticles with the nucleic acid (page 3, lines 2-15; Figs 1-4; page 21, line 8-page 22, line 29; Examples 5-10; claims 1, 11, 12, 15, 35, 36, 45, 46 and 49). The nanoparticles include metal such as silver (claims 10 and 44) and semiconductor materials, e.g., CdSe and CdS (page 19, lines 24-34; claims 2-5 and 37-39), and each nanoparticle has a plurality of oligonucleotides attached to it, thus each nanoparticle-oligonucleotide conjugate can bind to a plurality of nucleic acids having complementary sequence (page 22, lines 30-34; claims 8, 9, 42 and 43).

9. Claims 1-9, 11-13, 15, 16, 35-43, 45-47, 49 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Bawendi *et al.* (U. S. Patent 6,306,610, filed September, 1999).

Bawendi *et al.* teach a composition comprising a fluorescent semiconductor nanocrystal having an overcoating layer, associated with a compound that has affinity and can physically interact with a biological target such as proteins, nucleic acids, cells and subcellular organelles, wherein the affinity is hydrophilic, ionic or electrostatic attraction (column 4, line 7-column 5,

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line 8; claims 1, 2, 15, 16, 35, 36, 49 and 50), and wherein the compound having at least one linking group attached to the overcoating layer and at least one hydrophilic group has the structural formula (I), (II), (III) or (IV), where the hydrophilic group may be a charged group such as carboxylates, sulfonate, phosphates or ammonium salts (column 15, line 66-column 18, line 53; claims 8, 9, 11-13, 42, 43 and 45-47). The semiconductor nanocrystal includes a core surrounded by a semiconductor shell, and the core and the shell can be a semiconductor material including those of Group II-VI, e.g., CdSe and ZnS (column 6, lines 14-37; claims 3-7 and 37-41).

10. Claims 1-5, 8, 9, 11-12, 15, 16, 35-39, 42, 43, 45-46, 49 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Bawendi *et al.* (U. S. Patent 6,326,144, filed September, 1998).

Bawendi *et al.* teach a composition comprising a fluorescent semiconductor nanocrystal having an overcoating layer, associated with a compound that has affinity and can physically interact with a biological target such as proteins, nucleic acids, cells and subcellular organelles, wherein the affinity is hydrophilic, ionic or electrostatic attraction (column 3, line 31-column 4, line 4; claims 1, 2, 15, 16, 35, 36, 49 and 50), and wherein the compound having at least one linking group attached to the overcoating layer and at least one hydrophilic group, has the structural formula $H_zX((CH_2)_nCO_2H)_y$, where the hydrophilic group is carboxylate (column 7, line 66-column 8, line 51; claims 8, 9, 11-12, 42, 43 and 45-46). The semiconductor nanocrystal includes semiconductor materials of Group II-VI, e.g., CdSe and ZnS (column 6, lines 14-37; claims 3-5 and 37-39).

Conclusion

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11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

August 6, 2003

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800